

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. {redacted}V

Filed: April 30, 2007

Reissued on May 14, 2007

Not for Publication

JOHN DOE/01,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Respondent.

*
*
*
*
*
*
*
*
*

Hepatitis B vaccine;
Causation in fact; Decision
on the Record;
Neurological Injury

Thomas Gallagher, Esq., Gallagher & Gallagher, Somers Point, NJ, for petitioner.
Alexis Babcock, Esq., U.S. Department of Justice, Washington D.C., for respondent.

Denise K. Vowell, Special Master:

DECISION¹

On {redacted}, Mr. John Doe/01 filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² [the “Vaccine Act” or “Program”] alleging that hepatitis A and B vaccines he received on

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

² Hereinafter, for ease of citation, all “§” references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

January 8, February 6,³ and July 16, 2002 caused him to develop unspecified “neurological injuries.” Petition [“Pet.”] at 1. None of the statutorily required supporting documentation accompanied the petition.⁴ Accordingly, the special master to whom the case was then assigned ordered petitioner to file medical records and an affidavit by November 11, 2005. After petitioner sought and received an enlargement of time, he filed medical records (Pet. Ex. A-K).⁵ Petitioner’s affidavit [“Pet. Aff.”] was filed on February 21, 2006, but was not assigned an exhibit number. In a status conference held that same day, petitioner’s case was set for an onset hearing on May 10, 2006. On March 14, 2006, petitioner filed additional exhibits (Pet. Ex. L-M) and the affidavit of Mr. {H}{redacted}, also not assigned an exhibit number.

This case was reassigned to me on April 5, 2006. I conducted a status conference with the parties on May 1, 2006, and based on representations from counsel that separate onset and causation hearings were not warranted, I determined that the onset hearing scheduled for May 10, 2006 was not necessary. I ordered petitioner to file the report of a medical expert by June 30, 2006 and ordered respondent to file a Rule 4 report by May 30, 2006. Order, dated May 2, 2006. Respondent filed her Rule 4 report on May 8, 2006. For the last 10 months, the court has been attempting to get petitioner to file the report of a medical expert.⁶

³ The petition also identifies the date of the second vaccination as February 2, 2002. Pet. at ¶ 2. Based on the vaccination records at Petitioner’s Exhibit [“Pet. Ex.”], C pp. 82-83, the February 6, 2002 date is correct. Petitioner received three doses of Twinrix, an immunization containing both hepatitis A and hepatitis B vaccines.

⁴ Section 300aa–11(c) of the Vaccine Act requires the petition to be accompanied by certain documentary evidence, including records pertaining to the vaccination and subsequent treatment. See *also*, Vaccine Rule 2(e), RCFC, Appendix B.

⁵ Although petitioner’s counsel is experienced in handling Vaccine Act cases, for some reason, he lettered petitioner’s exhibits, rather than assigning numbers to them. The Guidelines for Practice Under the National Vaccine Injury Compensation Program, which can be found at <http://www.uscfc.uscourts.gov/OSMPage.htm>, provides on page 7 that the documents submitted by petitioners must be organized into separately numbered exhibits (emphasis added). Additionally Pet. Ex. A-K are sequentially numbered, without beginning the page numbers anew with each exhibit. The exhibits are not separately tabbed, making this filing even more confusing to reference.

⁶ Petitioner missed the June 30, 2006 deadline and failed to file a request for an extension of time. Accordingly, at the previously scheduled status conference on July 10, 2006, I discussed petitioner’s failure to file the expert report and advised petitioner’s counsel of the requirement to file requests for extensions of time (including the level of detail expected in such requests and the Vaccine Rule 19(b) requirement to confer with opposing counsel about objections to the extension). I set a new deadline of August 9, 2006 for the expert report, based on counsel’s indication that he could file the report within 30 days. On August 14, 2006, petitioner’s counsel filed a late status report indicating that the expert report had not yet been received. In response, I set yet another deadline, September 9, 2006, for petitioner’s expert report, and reminded him once again of the requirements to file timely requests for extensions of time and to confer with opposing counsel. Once again, petitioner filed a late request for an extension of time, this time on September 11, 2006. Because counsel advised me that the doctor who had reviewed

After numerous attempts, detailed in footnote 6, above, to obtain an expert report from petitioner, I issued a show cause order on March 8, 2007. In that order, I set forth what had transpired in a January 9, 2007 status conference. Essentially, petitioner's counsel indicated that he had been unable to find an expert to opine favorably for petitioner. He requested one additional opportunity to obtain an expert report, indicating that he would either file the report or a motion for judgment on the record by February 28, 2007. Neither was filed. I therefore ordered petitioner to show cause by March 26, 2007, why his case should not be dismissed for failure to comply with court orders or failure to substantiate his claim.

On March 21, 2007, petitioner requested that I rule on the petition based on the existing record, noting that he had been unable to find an expert to support his case. Respondent has interposed no objection to this request.

Having considered the entire record, I conclude that petitioner has failed to demonstrate his entitlement to compensation.

DISCUSSION

In order to prevail under the Program, petitioner must prove either a "Table"⁷ Injury or that a vaccine listed on the Table was the cause in fact of an injury. Petitioner did not suffer a "Table" Injury. While Pet. Ex. B, pp. 82-83 establish that he received three doses of Twinrix, no evidence submitted links petitioner's vaccinations to any illness, disability, injury, or condition. See § 300aa-11(c)(1)(C)(i).

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion. See § 300aa-13(a)(1). Petitioner has failed to proffer medical records or an expert opinion causally linking his medical condition to any

the case was unwilling to opine on causation and he wished to send the case to another expert, on September 14, 2006, I granted the 45 day extension petitioner had requested and set a new deadline of October 24, 2006 to obtain an expert report. On October 18, 2006, petitioner requested another 45-day extension, indicating that the expert reviewing the case was on vacation and that he had not been able to find another expert to review the case by the deadline. On November 1, 2006, petitioner renewed his request for an additional 45 days to obtain an expert report. The matters that transpired between the two requests are detailed in my Order, dated November 27, 2006. I noted that the requested enlargement did not indicate that named expert had agreed to offer an opinion. I ordered petitioner's counsel to contact my chambers to schedule a status conference within three days of any declination by the named expert. I granted an extension until February 28, 2007 for petitioner to file the expert report or a statement from the named expert indicating when the report would be completed.

⁷ A "Table" Injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. The hepatitis A and B vaccines are listed on the Table; however petitioner's medical condition is not an injury specified for compensation for that vaccine.

vaccine.

To satisfy his burden of proving causation in fact, petitioner must “show by preponderant evidence that the vaccination brought about [his] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). See also, *Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). He must show “that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.” *Grant*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Without more, “evidence showing an absence of other causes does not meet petitioner’s affirmative duty to show actual or legal causation.” *Grant*, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. See *Hasler v. U.S.*, 718 F.2d 202, 205 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984).

Prior to receipt of the Twinrix vaccinations, petitioner had a history of depression and anxiety. Pet. Ex. A, pp. 4-5. He received Twinrix vaccinations on January 8, February 6, and July 16, 2002. Pet. Ex. C, pp. 82-83. He was diagnosed with cellulitis and plantar fasciitis on September 18, 2002. *Id.*, pp. 84-85. He returned with some alcohol-related problems on October 1, 2002. *Id.*, p. 87.

The first indication of any neurological disease or injury was on October 9, 2002, when he reported intermittent left-side tingling for the previous few days; left hand tingling over the last year after a fall from a roof, and a mild headache similar to those he had previously experienced. *Id.*, pp. 92-93. An MRI two days later showed nonspecific white matter changes with “a broad differential diagnosis including demyelinating disease.” *Id.*, p. 97. A subsequent neurological exam was normal, but the examining neurologist, Dr. Machteld Hillen, considered possible diagnoses of multiple sclerosis [“MS”],⁸ vasculitis, or an old viral infection, and ordered additional testing. *Id.*, pp. 103-04. Upon return to Dr. Hillen on October 30, 2002, petitioner had declined several tests for financial reasons,⁹ and Dr. Hillen spent most of the visit dealing with petitioner’s questions about the possible MS diagnosis. Doctor Hillen stressed that she had not made such a diagnosis. *Id.*, p. 120. She referred petitioner

⁸ Multiple sclerosis is “a progressive disease characterized by disseminated demyelination of nerve fibers of the brain and spinal cord.” Early symptoms include abnormal sensations in the extremities or face, vertigo, visual disturbances, and muscle weakness. Later symptoms include ataxia (an abnormal or staggering gait). *Mosby’s Medical Dictionary* at 1234 [“*Mosby’s Medical Dictionary*”] (7th ed. 2006).

⁹ In later records, petitioner indicated in a medical history that he did not have all the ordered tests because he feared a possible MS diagnosis. Pet. Ex. F, p. 156.

for a spinal MRI, which was read as normal. *Id.*, p. 121.

At a followup visit on December 18, 2002, petitioner reported that his symptoms had worsened. Doctor Hillen noted that petitioner had not previously described his psychiatric history or that he had stopped taking Prozac around the time of his earlier visits. She described petitioner as very anxious, tearful, and fearful. She stated: “The patient’s multitude of symptoms that he is having now are definitely not related to the mild white matter lesions that he has on his brain MRI. In addition, his neurological exam is entirely within normal limits. The disappearance of his symptoms when patient is reassured and gets attention, pleads against a neurologic underlying problem as a cause of these spells.” *Id.*, pp. 123-24.

Although petitioner has been seen by a number of medical professionals over the intervening forty months for a wide variety of symptoms, none have diagnosed MS or any other neurological condition. *See generally*, Pet. Ex. A-M. Another neurologist also suggested that petitioner’s symptoms might be psychosomatic versus a pathological problem. Pet. Ex. C, p. 134. The last neurology records filed date from October and November, 2005. The neurologist, Dr. Norman Latov¹⁰, initially recorded a suspicion of central nervous system problems. Pet. Ex. L, pp. 207-08. After numerous diagnostic tests, he entertained a diagnosis of celiac disease¹¹ and referred petitioner for an endoscopy and duodenal biopsy. *Id.* at 206. After testing, petitioner was diagnosed with that condition. Pet. Ex. M, pp. 225-26.

No medical record or opinion relates petitioner’s neurologic or digestive complaints to the hepatitis A or B vaccines. Despite ample opportunities to do so, he has failed to find a medical expert to opine favorably on causation. The affidavit of Mr. {H} documents a decline in petitioner’s health, beginning in October 2002. It does not document a causal connection between vaccine and injury. Petitioner’s affidavit differs from the contemporaneous records of Dr. Hillen concerning petitioner’s diagnosis. Petitioner connects his subsequent illness to the vaccinations. Pet. Aff. ¶ 28. However, petitioner’s beliefs are not a sufficient basis upon which to award compensation.

While close calls regarding causation must be resolved in favor of the petitioner, *Althen*, 418 F.3d at 1280, in this case petitioner has completely failed to meet his burden to establish vaccination causation for his injury.

¹⁰ I note that Dr. Latov was approached to offer a medical opinion on causation in this case and apparently declined to do so. *See* Motion to Enlarge Time, dated November 11, 2006 and Certification in Support of Petitioner’s Motion. *See also*, Order, dated November 27, 2006.

¹¹ Celiac disease is a malabsorption syndrome characterized by intolerance to gluten-containing foods. It is sometimes referred to as sprue. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY [“DORLAND’S”] at 530 (30th ed. 2003).

CONCLUSION

A special master can only authorize compensation when a medical condition either constitutes a “Table” injury or when some evidence, such as a reliable medical opinion, causally connects the vaccine with the injury. No such proof exists in the record before me. Therefore, the petition for compensation is DENIED. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance with this decision.¹²

IT IS SO ORDERED.

Denise K. Vowell
Special Master

¹² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party’s filing a notice renouncing the right to seek review.